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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/732,241 | 12/07/2000 | Mathai Mammen | P-095-US1 | 9496 |
| 27038 | 7590 | 05/23/2005 | EXAMINER | |
| THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080 | | | COVINGTON, RAYMOND K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/732,241 | Applicant(s) MAMMEN ET AL. | |
| | Examiner Raymond Covington | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

PD

The rejection under 35 USC 112 2nd paragraph to claim 47 has been overcome in light of applicants' amendment.

The rejection under 35 USC 112 1st paragraph to claims 48-49 has been overcome in light of applicants' cancellation of claims 48-49.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 are again rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement and lacking enablement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants' comments have been noted and considered but are not deemed persuasive of patentability. It is noted that substituents R_x, R⁴, R⁵, B, Z, R, R', R'', R²⁷, R³⁶, R³⁷, R⁴⁶ and R⁴⁷ are drawn to, for example heteroaryl, heterocycloamino, heteroarylene, heterocyclene, heteroaryl,

heterocyclic, heteraryloxy, heteroarylthio, heterocyclyl, heterocycloxy, heteroaralkyl, thioheteraryloxy and thioheterocycloxy are not sufficiently described or enabled in the specification. It is recognized that the "A" ring has been defined as being phenyl and pyridine. Likewise, the examples applicants' refer to in the specification tables are drawn to the X "linker" and not to the moieties and their substituents.

Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 are recite the limitation "linker" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It is not clear what the term "linker" means in the context of the claims and the specification.

Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 are recites the limitation "attaches(a)" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It is not clear what the term means or refers to in the claim.

Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

L₁ as defined by formula (a) in claim 1 lacks a point of attachment rendering the claims indefinite.

The objection to claims 22, 33 and 46 have been rendered moot by their cancellation.

The obviousness-type double patenting rejection of claims 24-26 and 51 has been overcome by the filing and approval of a terminal disclaimer.

No claim has been allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RKC

Raymond Covington
Examiner
Art Unit 1625


5/19/05